RVD2008-32

Re-evaluation Decision

Mineral Oil

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Overview

Re-evaluation Decision

After a re-evaluation of the insecticide and acaricide mineral oil, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting continued registration of products containing mineral oil for sale and use in Canada.

An evaluation of available scientific information found that products containing mineral oil do not present unacceptable risks to human health or the environment when used according to label directions. As a condition of the continued registration of mineral oil uses, new risk-reduction measures must be included on the labels of all products.

The regulatory approach for the re-evaluation of mineral oil was first presented in Proposed Re-evaluation Decision document PRVD2008-19, *Mineral Oil*, a consultation document.[1] This Re-evaluation Decision document[2] describes this stage of PMRA's regulatory process for the re-evaluation of mineral oil as well as summarizes the Agency's decision and the reasons for it. Appendix I summarizes the comments received during the consultation process and provides the PMRA's response to these comments.

This decision is consistent with the proposed re-evaluation decision stated in PRVD2008-19. To comply with this decision, registrants of products containing mineral oil will be informed of the specific requirements affecting their product registrations and of regulatory options available to them.

What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA's pesticide re-evaluation program considers the potential risks as well as value of pesticide products, to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Mineral oil, one of the active ingredients in the current re-evaluation cycle, has been re-evaluated under Re-evaluation Program 1. This program relies as much as possible on foreign reviews, typically United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents. For products to be re-evaluated under Program 1, the foreign review must meet the following conditions:

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian regulatory decisions;
- it addresses the active ingredient and the main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

Based on the outcome of foreign reviews and a review of the chemistry of Canadian products, the PMRA has made a regulatory decision and requires appropriate risk-reduction measures for Canadian uses of mineral oil. In this decision, the PMRA took into account the Canadian use pattern and issues (e.g. the federal Toxic Substances Management Policy).

The USEPA re-evaluated mineral oil and published its conclusions in a 2007 RED.

For more details on the information presented in this Re-evaluation Decision, please refer to the Science Evaluation in the related Proposed Re-evaluation Decision PRVD2008-19, *Mineral Oil*.

What Is Mineral Oil?

Mineral oil is used as an insecticide and acaricide on agricultural crops (apples, apricots, cherries, highbush blueberries, ornamentals, peaches, pears, plums, prunes, rutabagas and Saskatoon berries). It is applied commercially using ground spray equipment such as airblast sprayers, hollow cone nozzles or groundboom. It can also be used by homeowners as an insecticide or fungicide on fruit trees and ornamentals. Homeowners can apply mineral oil using handheld equipment.

Health Considerations

Can Approved Uses of Mineral Oil Affect Human Health?

Mineral oil is unlikely to affect your health when used according to the revised label directions.

People could be exposed to mineral oil by consuming food and water, mixing/loading or applying it or by entering treated sites. The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

The USEPA concluded that mineral oil was unlikely to affect human health provided that risk-reduction measures were implemented. These conclusions apply to the Canadian situation and equivalent risk-reduction measures are required.

Maximum Residue Limits

The *Food and Drugs Act* prohibits the sale of food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in or on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Mineral oil is currently registered in Canada for use on apples, apricots, cherries, highbush blueberries, peaches, pears, plums, prunes, rutabagas and Saskatoon berries, and could be used in other countries on crops that are imported into Canada. No specific MRLs have been established for mineral oil in Canada. Where no specific MRL has been established, a default MRL of 0.1 ppm applies, which means that pesticide residues in a food commodity must not exceed 0.1 ppm. However, changes to this general MRL may be implemented in the future, as indicated in the Discussion Document DIS2006-01, *Revocation of the 0.1 ppm as a General Maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002(1)]*. If and when the general MRL is revoked, a transition strategy will be established to allow permanent MRLs to be set.

Environmental Considerations

What Happens When Mineral Oil Is Introduced Into the Environment?

Mineral oil is unlikely to affect non-target organisms when used according to the revised label directions.

Non-target species (e.g. birds, mammals, plants, honeybees, fish, oysters, daphnia) could be exposed to mineral oil in the environment.

The USEPA concluded that the reregistration of mineral oil was acceptable provided risk-reduction measures to further protect the environment were implemented. These conclusions apply to the Canadian situation, and equivalent risk-reduction measures are required in Canada. Furthermore, the PMRA requires aquatic buffer zones for mineral oil to protect aquatic organisms from spray drift.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law. As a result of the re-evaluation of mineral oil, the PMRA is requiring further risk-reduction measures for product labels.

Human Health

- Additional protective equipment to protect mixer/loader/applicators,
- A restricted-entry interval to protect workers entering treated sites.

Environment

- Buffer zones to protect non-target sensitive aquatic habitats.

Appendix II lists all required label amendments.

Other Information

Any person may file a notice of objection[3] regarding this decision on mineral oil within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the PMRA's website (Request a Reconsideration of Decision, www.pmra-arla.gc.ca/english/pubreg/reconsideration-e.html), or contact the PMRA's Pest Management Information Service by phone (1-800-267-3615) or by e-mail (pmra_infoserv@hc-sc.gc.ca).

[3] As per subsection 35(1) of the *Pest Control Products Act*.

Appendix I Comments and Responses

1.0 Comment

A comment was received that the term 'Pome fruit and stone fruit' was translated into the French term "Fruits à pépins et drupes" in PRVD2008-19, buffer zone table in section II, Appendix II. The comment also stated that 'stone fruit' is properly translated on the Termium Plus® web site as 'fruits à noyau' and 'drupe' is the same in both languages. The PMRA has considered this information in the response below.

Response

The PMRA has historically translated the term 'stone fruit' as 'fruits à noyau', and will continue to do so.

The French term has been corrected with the publication of this Re-evaluation Decision.

Appendix II Label Amendments for Products Containing Mineral Oil

The labels of end-use products in Canada must be amended as follows to further protect workers and the environment.

I) The following statements must be included in a section entitled **PRECAUTIONS**.

Wear a long-sleeved shirt, long pants, and shoes and socks during mixing, loading, application, clean-up and repair.

Do not enter or allow others to enter treated areas during the restricted-entry interval (REI) of 12 hours.

II) The following statements must be included in a section entitled **DIRECTIONS FOR USE**.

Buffer Zones:

Uses of the following spray methods or equipment DO NOT require a buffer zone: handheld or backpack sprayer and spot treatment.

When a tank mixture is used, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture.

Field sprayer application: DO NOT apply during periods of dead calm. Avoid application of this product when winds are gusty. DO NOT apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) fine classification. Boom height must be 60 cm or less above the crop or ground.

Airblast application: DO NOT apply during periods of dead calm. Avoid application of this product when winds are gusty. DO NOT direct spray above plants to be treated. Turn off outward pointing nozzles at row ends and outer rows. DO NOT apply when wind speed is greater than 16 km/h at the application site as measured outside of the treatment area on the upwind side.

DO NOT apply by air.

The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and estuarine/marine habitats.

Method of application	Crop	Buffer Zones (metres) Required for the Protection of:			
		Freshwater Habitat of Depths:		Estuaries/Marine Habitats of Depths:	
		Less than 1 m	Greater than 1 m	Less than 1 m	Greater than 1 m
Field sprayer*	Highbush blueberries, rutabaga	2	1	1	1
Airblast	Prunes, Saskatoon berries	4	2	1	0
	Ornamental plants, shade trees and shrubs	5	3	1	0
	Pome fruit and stone fruit	20	10	3	1

* For field sprayer application, buffer zones can be reduced with the use of drift reducing spray shields. When using a spray boom fitted with a full shield (shroud, curtain) that extends to the crop canopy, the labelled buffer zone can be reduced by 70%. When using a spray boom where individual nozzles are fitted with cone-shaped shields that are no more than 30 cm above the crop canopy, the labelled buffer zone can be reduced by 30%.

III) The following statements must be included in a section entitled **ENVIRONMENTAL HAZARDS**.

TOXIC to aquatic organisms: Observe buffer zones specified under **DIRECTIONS FOR USE**.

For terrestrial uses: Do not apply directly to water, or to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate.

Drift and runoff may be hazardous to aquatic organisms in water adjacent to treated areas.

References

Studies considered in the Chemistry Assessment

A. LIST OF STUDIES/INFORMATION SUBMITTED BY REGISTRANT

Unpublished Information

PMRA Document Number	Reference
1462612	Pest Management Regulatory Agency Data Screen Category B Submission B1.1 New Source by Same Registrant. MOI-SNF-8 , DACO: 2.1,2.10,2.11,2.12,2.13,2.14,2.15,2.16,2.2,2.3,2.4,2.5,2.6,2.7,2.8,2.9
1463016	Technical chemistry file - Description of Starting Materials, DACO: 2.11.2
1463017	Technical chemistry file - Detailed Production Process Description, DACO: 2.11.3
1463018	2000, Technical chemistry file - Discussion of the Formation of Impurities in Spray Oils 10, 15 and 22 and Confidential Attachment. Attachments 4, 5, 6, 7 and 8-Polynuclear aromatics contents determination through GC/MS - HT60, HT80, HT100, N65DW, HT160
1463021	2001, Technical chemistry file - Quantitative Determination of Hydrocarbon Types in Petroleum Distillates (Hig Resolution Mass Spectrometry) Spray Oil 10, 15 and 22, 000172-10-2;000172-15-2;000172-22-2, DACO: 2.13.1,2.13.2,2.13.3
1501277	Memos and Data on Shell Oarabase, Shell HVI 100, Shell HVI 250, 263887, DACO: 2.99
1462717	Technical Chemistry file - Petro-Canada Spray Oil 13, DACO: 2.99
1461222	Technical Chemistry file Mohawk Dormant Oil, DACO: 2.99

B. ADDITIONAL INFORMATION CONSIDERED

Published Information

US EPA, 2006, Memorandum Describing the Environmental Fate and Effect Division's Ecological Risk Assessment on Aliphatic Oils (PC Codes 063502 and 063503) in Support of Reregistration Eligibility Decision, DACO: 12.5

US EPA, 2007, Federal Register / Vol. 72, No. 243 / Wednesday, December 19, 2007 / Notices, DACO: 12.5

US EPA, 2007, US Environmental Protection Agency Office of Pesticide Programs - Revised Reregistration Eligibility Decision for Aliphatic Solvents. Revised Reregistration Eligibility Decision Exposure and Risk Assessment on Lower Risk Pesticide Chemicals.

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